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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
DANG, IAN D	
ART UNIT	PAPER NUMBER
1647	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/644,703	PENA ET AL.	
	Examiner	Art Unit	
	IAN DANG	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 August 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,12-26,32,34-38 and 46-59* is/are pending in the application.

4a) Of the above claim(s) *1-7,21-26 and 46-59* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8,9,12-20,32 and 34-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 August 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments and/or Claims

The amendment of 19 August 2008 has been entered in full. Claims 10-11, 27-31, 33, and 39-45 have been cancelled and claims 35 and 36 have been amended. Claims 1-7, 21-26, and 46-59 drawn to a non-elected invention have been withdrawn.

Claims 8, 9, 12-20, 32, 34-38 are under examination.

Specification

The disclosure is objected to because of the following informalities:

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (see page 12, line 8). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Appropriate correction is required.

Please note that this rejection was already presented at page 3 of the office action mailed 06/09/2008 and has not been addressed in the response filed 08/19/2008.

Sequence Compliance

According to 37 CFR 1.821(d) (MPEP § 2422), where the description or claims of a patent application discuss a sequence listing that is set forth in the "Sequence Listing" in accordance with paragraph (c) of this section, reference must be made to the sequence by use of the assigned identifier, in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent application. Sequences appear in Figures 1 and 2, but they are not identified by SEQ ID NO in the figures themselves or in the

description on page 9 of the specification as required.

On page 37 of the specification, the description of the drawings for Figures such as 4, 7, and 8 which have various parts, need to be identified as such in the brief description (ex. “Figures 4A-B…”).

Claim Objections

Claims 13, 14, 15, 19, and 20 are objected to because of the following informalities:

Claims 13 and 14 are objected to because the recitation of "the heparin-binding growth factor receptor” implies the presence of only 1 receptor. Applicants can obviate the objection of claims 13 and 14 by reciting "a heparin-biding growth factor receptor".

Claim 15 is objected to because claim 15 should recite “wherein J1 is and, if n=1, both J1 and J2 are, diamine amino acid residues.” In addition, similar changes should be made to claims 19 and 20.

Appropriate correction is required.

Rejections Maintained

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re*

Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 8, 9, 12-20, 32, 34-38 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 7,166,574. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are both drawn to a synthetic heparin-binding growth factor (HGBF) analog.

The terminal disclaimer filed 09/22/2008 has not been approved because the attorneys are not of record.

Claim Rejections - 35 USC § 112, Second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 35 and 36 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

At page 11 of the response Applicants indicated that claims 35 and 36 are amended as a result to address the lack of antecedent in each claim.

Although Applicants have amended claims 35 and 36 to address the lack of antecedent basis in each claim, the claims remain rejected because the issue is not a lack of antecedent

basis in the claim but rather than the claims are indefinite over the recitation of "biological response."

More specifically, claims 35 and 36 are indefinite because it is unclear as to what the recitation of "biological response" in claims 35 and 36 is intended to encompass. For instance, the claimed biological response can be any response, since the specification has not provided any definition for, or sufficient examples of, the claimed "biological response".

Please note that this rejection was already presented at page 6 of the office action mailed 06/09/2008.

New Grounds of Rejection

Claim Rejections - 35 USC § 112 (Written Description)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13, 14, 34, 35, and 36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

1. Although Applicants provide the functional characteristics of the HBGF analog by reciting that the HBGF analog of formula II initiates a signal by the HBGF receptor (claim 13) and by reciting that the HBGF analog of formula II is a positive modulator of a biological response (claim 35), Applicants have not satisfied the written description requirements because Applicants have not provided the structural identifying characteristics of the HBGF analog of

formula II that can initiate a signal by a HBGF receptor and can be a positive modulator of a biological response. Neither the specification or the claim provide the common structural characteristics of the HBGF analog of formula II that is expected to initiate a signal by a HBGF receptor and be a positive modulator of a biological response. Thus, Applicants have not provided any identifying characteristics or properties of the instant HBGF analog of formula II that would be expected to have these activities such that one of skill would be able to predictably identify the claimed HBGF analogy encompassed by the instant claims.

Based on Applicants' disclosure and knowledge within the art, those of skill in the art would conclude that Applicants would not have been in possession of the claimed genus of HBGF analog of formula II that would be expected to have these 2 activities based on the disclosure of the species that include, F2A3 and F2A4, (pages 35-40, Examples 1-10), and relevant identifying characteristics. Thus, applicant was not in possession of the claimed genus and the written description requirement is not satisfied.

2. Although Applicants provide the functional characteristics of the HBGF analog by reciting that the HBGF analog of formula II blocks a signal by the HBGF receptor (claim 14), HBGF analog is an antagonist of the HBGF receptor (claim 34), and by reciting that the HBGF analog of formula II is a negative modulator of a biological response (claim 36), Applicants have not satisfied the written description requirements because Applicants have not provided the structural identifying characteristics of the HBGF analog of formula II that can block a signal by a HBGF receptor, can be an antagonist of the HBGF receptor, and can be a negative modulator of a biological response. Neither the specification or the claim provide the common structural characteristics of the HBGF analog of formula II that is expected to block a signal by a HBGF receptor, to be an antagonist of the HBGF receptor, and to be a negative modulator of a

biological response. Thus, Applicants have not provided any identifying characteristics or properties of the instant HBGF analog of formula II that would be expected to have these activities such that one of skill would be able to predictably identify the claimed HBGF analog encompassed by the instant claims.

Based on Applicants' disclosure and knowledge within the art, those of skill in the art would conclude that Applicants would not have been in possession of the claimed genus of HBGF analog of formula II that would be expected to have these 3 activities based on the disclosure of the species that include, F2A3 and F2A4, (pages 35-40, Examples 1-10), and relevant identifying characteristics. Thus, applicant was not in possession of the claimed genus and the written description requirement is not satisfied.

3. Applicants have not satisfied the written description requirements because Applicants have not provided any correlation between the different R_6 of the HBGF analog of formula II and their abilities to retain the biological activity of a heparin binding growth factor. Although claim 8 recites that R_6 is an aliphatic C_1 to C_{17} chain, the specification or the claim provide the common structural core structure of R_6 in the HBGF analog of formula II that is expected to have the biological function of HBGF. Thus, Applicants have not provided any identifying characteristics or properties of the instant aliphatic chain R_6 that would be expected to have HBGF activity such that one of skill would be able to predictably identify the claimed aliphatic chain R_6 encompassed by the instant claims.

Based on Applicants' disclosure and knowledge within the art, those of skill in the art would conclude that Applicants would not have been in possession of the claimed genus of aliphatic chain for R_6 of the HBGF analog of formula II that would be expected to have HBGF

activity. Thus, applicant was not in possession of the claimed genus and the written description requirement is not satisfied.

Claim Rejections - 35 USC § 112 (Enablement)

Claims 13, 14, 34, 35, and 36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Although Applicants have provided the HBGF analog of formula II, Applicants have not provided the common structural feature for the HBGF analog of formula II that would be expected to initiate a signal by a HBGF receptor and be a positive modulator of a biological response or to block a signal by a HBGF receptor, to be an antagonist of the HBGF receptor, and to be a negative modulator of a biological response. Without the disclosure of identifying structural features of the HBGF analog of formula II, it would require undue experimentation to make the claimed HBGF analogy of formula II because one of skill in the art would not know how to determine the structure of the HBGF analog of formula II that can initiate a signal by a HBGF receptor and be a positive modulator of a biological response or to block a signal by a HBGF receptor, to be an antagonist of the HBGF receptor, and to be a negative modulator of a biological response.

In addition, Applicants have provided 2 examples for the HBGF of formula II, F2A3 and F2A4, (pages 35-40, Examples 1-10) and these 2 examples have a common basic structure having R6 and Y as having 2 or 3 amino hexanoic acids, and X having SEQ ID NO:6 (F2A4) and SEQ ID NO:7 (F2A3). However, these 2 examples are not commensurate with the scope

the claims because the HBGF analog of formula II recited in the claims have not been shown to have any functional activities, such as initiating a signal by a HBGF receptor and being a positive modulator of a biological response or blocking a signal by a HBGF receptor, being an antagonist of the HBGF receptor, and being a negative modulator of a biological response.

Moreover, the state of the art indicates that changes in the structure of HBGF alter its activity. As disclosed at page 9 of the previous office action (06/29/2007), members of a class having structural homologies in common do not always share functional attributes although the disclosed heparin analogs of formula II share several common structural features. For instance, references in which heparin- binding domains of growth factors have been manipulated or mutated (Yoneda, et al, 2000, Nature Biotech., 18: 641-644; Verrecchio, et al, 2000, J. Biol. Chem., 275(11): 7701-7707) result in functionally-different compounds. This reference illustrates that it is not predictable as to which amino acids and analogs are necessary to maintain the functional characteristics of a synthetic peptide analog.

Furthermore, the specification does not provide any evidence that the HBGF analog of formula II recited in the claims have the biological activities as recited in claims 13, 14, 35, and 36. The specification and claims provide general teachings regarding the structure of the HBGF analog but do not provide any guidance regarding the ability of the HBGF analog of formula II to initiate a signal by a HBGF receptor and be a positive modulator of a biological response or to block a signal by a HBGF receptor and be a negative modulator of a biological response. For instance, the specification discloses 2 examples for the structure of an HBGF analog but does not provide any guidance regarding the functional activity for these 2 HBGF analogues.

Finally, although claim 8 recites that R_6 is an aliphatic C_1 to C_{17} chain, the specification does not provide guidance regarding the common feature of the aliphatic chain R_6 for the HBGF analog of formula II that would be expected to have HBGF activity. Without the disclosure of the

common core structure for R_6 , it would require undue experimentation to make the claimed HBGF analogy of formula II because one of skill in the art would not know how to determine the length for the aliphatic chain of R_6 with the ability to have HBGF activity.

Conclusion

No claim is allowed.

Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to IAN DANG whose telephone number is (571)272-5014. The examiner can normally be reached on Monday-Friday from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ian Dang
Patent Examiner
Art Unit 1647
November 9, 2008

/Robert Landsman/
Primary Examiner, Art Unit 1647